



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

km

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/687,230 10/13/00 BRASELMANN

S ONYX1027-DIV

EXAMINER

HM12/0328

GREGORY GIOTTA PH D
VICE PRESIDENT AND CHIEF LEGAL COUNSEL
ONYX PHARMACEUTICALS INC
3031 RESEARCH DRIVE
RICHMOND CA 94806

TUNG, P

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

03/28/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/687,230

Applicant(s)
Brasemann

Examiner
Peter Tung

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 8-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 8-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

1. Claims 8-12 are pending.

Specification

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): the sequence on page 9, line 27 is not identified by a SEQ ID NO:.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 8 is indefinite as it is unclear what is meant by an intermediate SH2 domain. Additionally, what "SH2" represents should be identified.

6. The term "bromodomain" in claim 9 is a relative term which renders the claim indefinite. The term "bromodomain" is not defined by the claim, the specification does not provide a

Art Unit: 1652

standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification only identifies bromodomain as amino acids 151 to 313 of SEQ ID NO: 2 or may be involved in protein-protein interactions (page 10, lines 21-25).

7. Claim 10 is indefinite as the claim is drawn to an amino acid sequence shown in Figure 2 or an amino acid sequence encoded by the cDNA shown in Figure 1. The instant specification does not disclose Figures 1 or 2 or a Brief Description of the Several Views of the Drawings.

8. The terms "Glu tag" and "myc epitope tag" in claim 12 are relative terms which render the claim indefinite. The terms "Glu tag" and "myc epitope tag" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Claim 11 is indefinite because it depends upon an indefinite base claim and fails to correct the problem.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated phosphatidylinositol-3' kinase associated protein comprising the amino acid sequence of SEQ ID NO: 2 or encoded by SEQ ID NO: 1, does not reasonably provide enablement for any phosphatidylinositol-3' kinase associated protein that binds

Art Unit: 1652

to the intermediate SH2 domain on the regulatory subunit of phosphatidylinositol-3' kinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claim encompasses any phosphatidylinositol-3' kinase associated protein that binds to the intermediate SH2 domain on the regulatory subunit of phosphatidylinositol-3' kinase.

However, insufficient guidance and examples are provided on any other phosphatidylinositol-3' kinase associated protein besides that of SEQ ID NO: 2 or encoded by SEQ ID NO: 1. The skill of those in the art is low in making phosphatidylinositol-3' kinase associated protein that binds to the intermediate SH2 domain on the regulatory subunit of phosphatidylinositol-3' kinase based only upon the amino acid and nucleic acid sequence of one such phosphatidylinositol-3' kinase associated protein. There is unpredictability in making such a protein without any guidance on how another such phosphatidylinositol-3' kinase associated protein besides that of SEQ ID NO: 2 can be obtained and from what sources one would find these proteins. Undue experimentation

Art Unit: 1652

would be required to enable the full scope of the claims based upon the limited scope of the disclosure.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

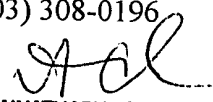
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Felder et al. Felder et al. teach (page 1451, Table 1; page 1452, Table 2) phosphatidylinositol-3' kinase associated proteins which bind SH2 domains on the regulatory subunit, which is that of the instant claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600